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MAR 20 2008

BIOMET
ORTHOPEDICS, INC.

510(k) Summary

Parallel-Sided Extensively Coated Femoral Stem

Preparation Date: December 21, 2007

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Elizabeth Wray

Proprietary Name: Parallel-Sided Extensively Coated Femoral Stem

Common Name: Hip joint femoral replacement device

Classification Name: - Class II, 21 CFR §888.3358, §888.3350, and §888.3353.

The mating components (modular heads and acetabular shells/liners) for use with the Parallel-Sided Extensively Coated Femoral Stem have the following classifications:

- Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer (888.3310)
- Prosthesis, Hip, Semi-constrained, Metal/Polymer, Cemented (888.3350)
- Prosthesis, Hip, Semi-constrained, Metal/Ceramic/Polymer, Cemented or Non-porous, Uncemented (888.3353)
- Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous, Uncemented (888.3358)
- Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented (888.3390)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Reach® Revision System- K982367, 08/24/98 (Biomet Inc.)
AML® Hip Stem- K012364, 10/19/01 (DePuy Inc.)
XR-Series Bi-Metric® Femoral Stems- K052089, 02/17/06 (Biomet Inc.)

Device Description:

The Parallel-Sided Extensively Coated Femoral Stem is designed to replace the patient's natural femoral hip component due to disease or accident. The femoral hip prosthesis is made from wrought titanium alloy (Ti-6Al-4V) (ASTM F136) and has a porous coat, designed to be used in uncemented applications. The stem diameters and lengths are within the range of the previously cleared predicates. In addition to the cylindrical stem design, the Parallel-Sided Extensively Coated Femoral Stem offers a lateralized offset for optimal patient fit.

P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800 348 9500
Office: 574 267 6639
Main Fax: 574 267 8137
www.biomet.com

Indications for Use/Intended Use:

1. Non-Inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision of previous failed total hip arthroplasty.

The Parallel-Sided Extensively Coated Femoral Stems are for uncemented applications only.

Summary of Technologies:

The technological characteristics (materials, design, sizing, and indications) of the Parallel-Sided Extensively Coated Femoral Stem are similar or identical to the predicate devices or to other previously cleared devices.

Non-Clinical Testing:

Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2008

Biomet Manufacturing Corp.
c/o Ms. Elizabeth Wray
Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K073637
Trade/Device Name: Parallel-Sided Extensively Coated Femoral Stems
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, LPH, JDI, KWY, KWZ
Dated: December 21, 2007
Received: December 26, 2007

Dear Ms. Wray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073637

Device Name: Parallel-Sided Extensively Coated Femoral Stems

Indications for Use:

1. Non-Inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
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The Parallel-Sided Extensively Coated Femoral Stems are for uncemented applications only.

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K073637